Aldara®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Aldara?

Aldara contains the active ingredient imiquimod. Aldara is used to treat solar keratosis (also known as actinic keratoses), superficial basal cell carcinoma and external genital/perianal warts (also known as condyloma acuminata).

For more information, see Section 1. Why am I using Aldara? in the full CMI.

2. What should I know before I use Aldara?

Do not use if you have ever had an allergic reaction to Aldara or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I use Aldara? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Aldara and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Aldara?

Your doctor will tell you where to apply Aldara, how often and for how long to apply it. Apply Aldara just before bedtime and leave on the skin for 6-10 hours. Sufficient cream should be applied to cover the treatment area.
More instructions can be found in Section 4. How do I use Aldara? in the full CMI and in the instruction leaflet provided in the carton.

5. What should I know while using Aldara?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Aldara • Call you doctor straight away if you become pregnant .
Things you should not do	• Do not use more than the recommended amount of Aldara • Do not cover the treatment area with bandages or other dressings after you have applied Aldara • Do not use sunlamps or tanning beds, and avoid going into the sun as much as possible • Do not apply on the eyes, lips, nostrils or to lesions on hands and arms when treating solar keratosis • Do not apply on the hairline, eyes, ears, nose, or lips when treating superficial basal cell carcinoma • Do not apply Aldara before any sexual (genital, anal or oral) contact when treating genital warts • Do not use Aldara for more than one course if you have problems with your immune system either due to illness or because of the medicines you are already taking when treating genital warts.
Looking after your medicine	• Keep Aldara in a cool dry place where the temperature stays below 25°C. Do not freeze. • Keep out of reach of children. • When using Aldara pump discard any remaining medicine 4 weeks after opening.

For more information, see Section 5. What should I know while using Aldara? in the full CMI.

6. Are there any side effects?

Common side effects: • Application site reactions including redness, wearing away of the skin, flakiness, swelling, hardening under the skin, small open sores, crust that forms during healing, small bubbles under the skin, itching, burning, pain, tenderness, irritation, rash, soreness, stinging, sensitivity, changes in skin colour, bleeding, lumps on the skin, infection and pimples • Other side effects include flu symptoms, tiredness, fever, headache, diarrhoea, back pain, muscle pain, and swollen glands in the neck, armpit and groin and mouth ulcers.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Aldara®

Active ingredient(s): *Imiquimod*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Aldara. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Aldara.**

Where to find information in this leaflet:

1. Why am I using Aldara?
2. What should I know before I use Aldara?
3. What if I am taking other medicines?
4. How do I use Aldara?
5. What should I know while using Aldara?
6. Are there any side effects?
7. Product details

1. Why am I using Aldara?

Aldara contains the active ingredient imiquimod. Imiquimod is an immune response modifier. It activates immune cells in the body. The immune cells then proceed to kill and remove the virus-infected or cancer cells.

Aldara is used to treat the following skin conditions:

- Solar keratosis (SK) on the face and scalp. Solar keratoses are thickened, scaly patches of skin caused by too much sun exposure. Solar keratosis is also known as actinic keratosis.
- Superficial basal cell carcinoma (sBCC) a type of skin cancer.
- External genital/perianal warts (condyloma acuminata) are warts that appear on the surface of the penis or vulva and around the anus.

2. What should I know before I use Aldara?

Warnings

Do not use Aldara:

- If you are allergic to imiquimod, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- On skin where there are open sores or wounds.
- On warts inside the vagina, anus or the urethra (where you pass urine).
- On sunburnt skin.
- On children under the age of 18 years.
- If the packaging is torn or shows signs of tampering.
- After the "use by" date shown on the box or sachet or after 4 weeks from first opening the Aldara pump.

Check with your doctor if you:

- Have any other medical conditions including but not limited to HIV, problems with your immune system or an abnormal blood count.
- Take any medicines for any other condition.
- Have previously used Aldara cream or other similar preparations to treat your condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or breastfeeding or intend to become pregnant or breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Aldara and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Aldara.

4. How do I use Aldara?

How much to use

Aldara is used to treat several skin conditions. Follow the specific instructions provided by your doctor on using Aldara for your skin condition. Sufficient cream should be applied to cover the treatment area. **Talk to your doctor if your condition re-appears after treatment.**

When using Aldara to treat Solar Keratosis (SK)

- Apply to the affected areas once a day, at bedtime, three times a week. For three times a week application, Aldara can be applied, for example, on Monday, Wednesday and Friday, or Tuesday, Thursday and Saturday.
- Your doctor may tell you to continue applying Aldara cream for 4 weeks, followed by a period of 4 weeks without any treatment. Your doctor will then check your skin condition. If any SK lesions remain, the treatment should be repeated for another four weeks.
- Alternatively, your doctor may want you to continue applying Aldara cream for up to 16 weeks. Do not continue treatment for longer than 16 weeks at a time.
- New SK lesions may develop during treatment with Aldara cream. These lesions may resolve during the treatment period. Even though the initial SK lesions may clear with treatment, new lesions may also develop in the future and require further treatment.

Aldara cream is not a cure since SK is considered to be a chronic skin condition.

When using Aldara to treat Superficial Basal Cell Carcinoma (sBCC)

- Apply to the affected area once a day at bedtime for five consecutive days per week (Monday to Friday), or as recommended by your doctor. Use enough cream to cover the treatment area, including one centimetre of skin surrounding the tumour. Continue treatment for 6 weeks unless your doctor tells you otherwise.
- Apply enough cream to cover the lesion and about 1 cm of the surrounding skin

When using Aldara to treat External Genital or Perianal Warts

- Apply a thin layer of cream once a day, at bedtime, three times a week or as recommended by your doctor.
- For three times a week application, Aldara can be applied on Monday, Wednesday and Friday; or Tuesday, Thursday and Saturday. Continue treatment until the warts are completely gone.
- Do not use Aldara for more than 16 weeks at a time. It usually takes 8-10 weeks for your warts to disappear, but warts may clear as early as 4 weeks. If your warts reappear, talk to your doctor.
- If your skin reacts badly to Aldara, your doctor may recommend that you stop treatment for a few days. It is not necessary to make up the doses that you missed or to prolong the treatment period.

How to use Aldara

Follow the step-by-step instructional leaflet provided in the carton on how to apply Aldara.

- Before applying Aldara, wash your hands and the treatment area with mild soap and water and allow it to dry thoroughly.
- After applying Aldara leave on the affected area for 6 to 10 hours. Do not shower or bathe during this time.
- After 6-10 hours, wash the area where Aldara was applied with mild soap and water.

If you forget to use Aldara

If you forget a dose, apply the missed dose of cream as soon as you remember and then continue on the regular schedule. Do not double the dose at any time to make up the missed dose.

If you use too much Aldara

Using too much Aldara could cause skin reactions. If you think that you have used too much Aldara, wash away the extra cream with mild soap and water. Continue treatment once any skin reaction has settled.

If the cream is accidentally swallowed, nausea, vomiting, headache, muscle pain, and fever could occur. **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Aldara?

Things you should know

- Aldara may weaken condoms and diaphragms. Wash the cream off before using a condom or diaphragm during sexual activity. Using an alternate form of contraception is recommended.
- Uncircumcised men with warts under the foreskin should pull the foreskin back each day and wash underneath it. If daily washing under the foreskin is not carried out, tightness of the foreskin may occur. Early signs of tightness include swelling and wearing away of the skin, or difficulty in pulling back the foreskin. If these symptoms occur, stop the treatment immediately and call your doctor.
- Female patients should take special care if applying Aldara cream at the opening of the vagina because local skin reactions on the delicate moist surfaces can result in pain or swelling and may cause difficulty in passing urine.

Things you should do

- Follow your doctor's instructions on where to apply Aldara, how often to apply it and for how long to apply it for your specific skin condition. Use Aldara until your doctor tells you to stop.
- Visit your doctor regularly if you are treating more than one Superficial Basal Cell Carcinoma (sBCC) lesion at the same time.

Call your doctor straight away if you:

- Become pregnant while using Aldara.

Remind any doctor, dentist or pharmacist you visit that you are using Aldara.

Things you should not do

- Do not use more than the recommended amount of Aldara. A thin layer (maximum 20 square centimetres) that completely covers the treatment area and surrounding skin is enough.
- Do not cover the treatment area with bandages or other dressings after you have applied Aldara unless your doctor tells you to. Cotton gauze dressings may be used, if needed.
- Do not use sunlamps or tanning beds and avoid going into the sun as much as possible while using Aldara. Wear protective clothing such as a wide-brimmed hat, long sleeve shirts, trousers or a long skirt if you go outside during daylight.
- Do not apply Aldara in or near the eyes, lips, nostrils or to lesions on the hands and arms or to an area

greater than 20 square centimetres when treating Solar Keratosis (SK).
- Do not apply Aldara in or near the hairline, eyes, ears, nose or lips when treating Superficial Basal Cell Carcinoma (sBCC).
- Do not engage in sexual (genital, anal or oral) contact when treating Genital Warts. If you decide to have sexual relations, apply Aldara cream after, not before, sexual activity. If you have already applied the cream, wash it off before sexual activity.
- Do not use Aldara for more than one course if you have problems with your immune system either due to illness or because of the medicines you are already taking when treating Genital Warts. If you think this applies to you, talk to your doctor.

Looking after your medicine

- Store Aldara below 25°C. Do not freeze.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard Aldara Pump

- Aldara pump must be discarded 4 weeks after opening.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use Aldara after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Some patients have experienced changes in skin colour (lighter or darker) in the area where Aldara was applied. These changes may be permanent in some cases.

Less serious side effects

Less serious side effects	What to do
Application site reactions including: • Redness • Wearing away of the skin • Flakiness • Swelling • Hardening under the skin • Small open sores	**Most of these skin reactions are mild to moderate, and are signs that the product is working. If your skin reacts badly or the skin reaction becomes too uncomfortable when using Aldara,**
• Crust that forms during healing • Small bubbles under the skin • Itching • Burning • Pain • Tenderness • Irritation • Rash • Soreness • Stinging • Sensitivity • Changes in skin colour • Bleeding • Lumps on the skin • Infection • Pimples	**wash the cream off with mild soap and water and contact your doctor. Your doctor may recommend that you stop treatment for a few days**

Other less serious side effects	What to do
• Flu symptoms • Tiredness • Fever or headache • Diarrhoea • Back or muscle pain • Swollen glands in the neck, armpit and groin • Mouth ulcers	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Aldara contains

Active ingredient (main ingredient)	imiquimod
Other ingredients	benzyl alcohol methyl hydroxybenzoate

(inactive ingredients)	propyl hydroxybenzoate isostearic acid cetyl alcohol stearyl alcohol white soft paraffin polysorbate 60 sorbitan monostearate glycerol xanthan gum purified water
Potential allergens	benzyl alcohol methyl hydroxybenzoate propyl hydroxybenzoate

Do not take this medicine if you are allergic to any of these ingredients.

What Aldara looks like

Aldara cream is a white to slightly yellow cream supplied in a pump pack or sachet..

The pump pack is supplied in a pack containing one or two pumps (AUST R 191815).

The sachets are supplied in a wallet containing 1 single-use foil sachet and in boxes of 6 and 12 single-use foil sachets (AUST R 64798).

Who distributes Aldara

iNova Pharmaceuticals (Australia) Pty Limited

Level 10, 12 Help Street

Chatswood NSW 2067

Tel: 1800 630 056

This leaflet was prepared in June 2026.